EXHIBIT A

MARK-UP VERSION OF REPLACEMENT ABSTRACT AND SPECIFICATION PARAGRAPHS

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ABSTRACT

[The present invention encompasses novel antibodies and fragments thereof which immunospecifically bind to one or more RSV antigens and compositions comprising said antibodies and antibody fragments.] The present invention encompasses methods preventing respiratory syncytial virus (RSV) infection in a human, comprising administering to said human a prophylactically effective amount of one or more antibodies or fragments thereof that immunospecifically bind to one or more RSV antigens, particularly palivizumab, wherein a certain serum titer of said antibodies or antibody fragments is achieved in said human subject. The present invention also encompasses methods for treating or ameliorating symptoms associated with a RSV infection in a human, comprising administering to said human a therapeutically effective amount of one or more antibodies or fragments thereof that immunospecifically bind to one or more RSV antigens, wherein a certain serum titer of said antibodies or antibody fragments is achieved in said human subject. [The present invention further encompasses compositions comprising antibodies or fragments thereof that immunospecifically bind to a RSV antigen, and methods using said compositions for detection or diagnosis a RSV infection.]

A humanized antibody directed to an epitope in the A antigenic site of the F protein of RSV, SYNAGIS® (*i.e.*, palivizumab), is approved for intramuscular administration to pediatric patients for prevention of serious lower respiratory tract disease caused by RSV at recommended monthly doses of 15 mg/kg of body weight throughout the RSV season (November through April in the northern hemisphere). SYNAGIS® is a composite of human (95%) and murine (5%) antibody sequences. See, Johnson et al., 1997, J. Infect. Diseases 176:1215-1224 and U.S. Patent No. 5,824,307, the entire contents of which are incorporated herein by reference. The human heavy chain sequence was derived from the constant domains of human IgG_1 and the variable framework regions of the VH genes or Cor (Press et al., 1970, Biochem. J. 117:641-660) and Cess (Takashi et al., 1984, Proc. Natl.

Acad. Sci. USA 81:194-198). The human light chain sequence was derived from the constant domain of Cκ and the variable framework regions of the VL gene K104 with Jκ-4 (Bentley et al., 1980, Nature 288:5194-5198). The murine sequences derived from a murine monoclonal antibody, Mab 1129 (Beeler et al., 1989, J. Virology 63:2941-2950), in a process which involved the grafting of the murine complementarity determining regions into the human antibody frameworks.

It should be recognized that antibodies that immunospecifically bind to a RSV antigen are known in the art. For example, SYNAGIS® (*i.e.*, palivizumab) is a humanized monoclonal antibody presently used for the prevention of RSV infection in pediatric patients. The present invention encompasses novel formulations for administration of SYNAGIS® and other known anti-RSV antibodies and novel doses of SYNAGIS® and other known anti-RSV antibodies, as discussed herein.